Town of Lexington

Office of Community Development
Health Division
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rDNA Application to obtain a *Permit* or to *Register* with the Lexington BOH

Date_____

Name of Applicant:		Phone:
Address of Applicant:		
City:	State:	Zip
Email Address:		
Signature of Applicant:		

Name of Person responsible for Lab Operations: Phone:
Email Address:
Address of Laboratory:

NOTE: All activities associated with the constructing and / or propagating recombinant DNA, (rDNA) molecules, organisms, viruses containing rDNA within the Town of Lexington are subject to the conditions of Article V, Use of Recombinant DNA Molecule Technology. Article VI, §155-34 Definitions states in part that Large scale: the use of more than Ten, (10) liters but less than five Thousand, (5,000) liters of rDNA culture.

Answer the following questions to complete the application process:

1. Specify the type of activities as defined in Article V.

Check off category	*Activity Description*	*Annual Fee*
	§155-36 Registration; Users whose experiments are all exempt from the NIH Guidelines. Users not constructing rDNA organisms but merely propagating them. A registration fee is due upon initial application and upon annual renewals.	$200.00
	§155-37 Permits; All institutions planning to use rDNA in any way other than those described under Registration must obtain a Permit from the Town of Lexington Board of Health with the final approval of the Lexington Biosafety Committee, (LBSC). A Permit fee is due upon initial application and upon annual renewals.	$500.00
	New Registration or New Permit: Submit all documentation as described under Plan Review for Registration or for Permit.	

2. Will it be necessary to use more than Five Thousand, (5,000) Liters of rDNA culture? If yes, then a variance must be obtained from the Lexington Board of Health.

3. Biological agents that are classified as requiring Biosafety Level 4, (BSL 4), shall not be permitted in the Town of Lexington. What is the Biosafety level for your institution?

4. Will safety glasses, lab coats, hand washing sinks or hand sanitizer or other personal protective equipment be available for staff or visitors to the lab?

5. Will animals be kept in the laboratory? If yes, then compliance must be achieved with Article VI, Animals.

Office of Community Development, Health Division use only:

PERMIT NUMBER_____ DATE RECEIVED_____ AMOUNT RECEIVED _____

APPROVED BY: _____ DATE: _____

New Registration – Plan Review & Submittal Requirements

§ 155-36. Registration states in part that rDNA users in the Registration category as described in Article V are required to submit the following;

:

1. A completed rDNA application.
2. A brief summary describing the proposed work including the name and type of organisms.
3. A reference to the section of the NIH Guidelines where the work falls.
4. If recombinant molecules containing eukaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
5. The scale (in filters) on which the organisms will be grown.
6. An assurance that all work will be carried out following the NIR Guideline, where applicable, at the appropriate BL level and that exempt work will be done at BL1.
7. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state and local codes.
8. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in Subsection B(2) above.

New Permit – Plan Review & Submittal Requirements

§ 155-37. PERMITS states in part that Institutions seeking such an rDNA permit from the Board of Health must first submit the following to the Lexington Biosafety Committee (LBSC):

1. A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.
2. A listing of all organisms, containment levels, and decontamination procedures to be employed.
3. A plan for a screening process to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process.
4. A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.
5. A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building. All waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, State Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.
6. A plan for systematic security of the premises.
7. Institutional Biosafety Committee (IBC). Describe the IBC in accordance with the guidelines of the Lexington Code.

   Note: The IBC shall meet a minimum of at least once per year. All minutes of the IBC meetings must be forwarded to the Board of Health and the LBSC.
8. Describe the institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the IBC for all persons engaged in the use of rDNA. See the Lexington Code for further information.
9. The name of the Principal Investigator responsible for enforcing the Policies of the IBC.
10. A plan for orienting representatives of the Lexington Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.
11. Written agreement to allow inspection of facilities and pertinent records by the LBSC.